

REMARKS

Applicants submit this response to the Office Action of March 2, 2006.

Claims 20-35 and 41-45 are pending.

1. The Examiner reopened prosecution after Applicants filed an Appeal Brief on January 18, 2006.

2. Applicants acknowledge that the following previous objections and rejections are now withdrawn:

(i) the rejection of claims 20-25 under 35 U.S.C. § 112, first paragraph, for recitation of new matter in claim 20; and

(ii) the rejection of claims 21-30, 34-35, 41-45 under 35 U.S.C. § 112, first paragraph, lack of enablement, for the recitation of "capable of."

3-5. Claims 41-45 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which has not been described in the specification in such a way as to reasonably convey to one skilled in the art that the inventions, at the time the application was filed, had possession of the claim invention.

The Examiner states that to provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors cited by the Examiner include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. However, no case law or precedent has been cited for these factors.

The Examiner states that there is allegedly no written description for claims drawn to a genus of polynucleotides that hybridize under conditions of moderate stringency to a nucleic acid which encodes a polypeptide comprising SEQ ID NO:3 or 6.

The Examiner further states that recitation of "high stringency" in claim 41 would not have obviated the rejection without reciting the conditions. Claims 41 recites the language of the specification at page 27, lines 24-30, wherein the sequences are "highly specific" and form "stable duplexes" with the target sequence. The sequences as described do not form duplexes with other regions of DNA. Applicants submit that

claim 41 as amended obviates the rejection, and as claims 42-45 depend from claim 41, the rejection of claims 41-45 may be withdrawn.

3. Claims 20-30, 34-35, 41-45 are rejected under 35 U.S.C. § 112, second paragraph.

Claim 20(c)-(d), lines 3-4 are allegedly vague and indefinite for the recitation of "complementary to ...," which encompasses fragments of the complement of SEQ ID NO:1 and 4 since the claim does not recite how many nucleotides there are in the complement or the length of the complement or the upper limit of the nucleotides in the complement. Applicants submit that this rejection has been obviated by amended claim 20 herein.

Claims 21-29 are allegedly vague and indefinite because they are dependent on claim 20 which recited that the claimed nucleic acids in the Markush group of claim 20(a)-(b) consist of nucleic acids consisting of SEQ ID NO:1 or 4 which nucleotide sequences are 489 base pairs. Applicants submit that the amendment to claim 20 clarifies this issue.

With respect to claims 41-45, the Examiner states that the specification does not recite "specifically hybridizes" and for that reason the amendment of December 8, 2004 was not entered. Applicants submit that "highly specific" and forming "stable duplexes" is equal in language for the term "specifically hybridizes" because hybridization means the formation of a duplex.

In view of the amendment of claim 20, claims 30 and 34-35 are not vague and indefinite.

4. Claims 20, 26, 30, 34, and 35 are rejected under 35 U.S.C. § 102(b) as being anticipated by Smith et al. (1991). This rejection was maintained for reasons of record set forth at page 7 of the Office Action of August 9, 2004 and pages 4-5 of the Office Action of March 31, 2004.

Applicants previously argued that the oligonucleotide of Smith comprising the sequence ATGAGAATTCGA would not specifically bind to a polynucleotide bound by the nucleic acids recited in claim 20 and would be outside the scope of the claims.

The Examiner now cites Kennell (1971), on page 261, lines 3-6 for the statement that the minimum size for a stable complex is 10 to 20 nucleotides. The Examiner

further states that the 12 nucleotides of the reference will bind with specificity and stability because the 12 nucleotides of the reference are perfectly complementary to nucleotides 1-13 of SEQ ID NO:1.

In order for a reference to anticipate a claim, “a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently.” Glaxo Inc. v. Novopharm Ltd. 52 F.3d 1043, 1047, 34 U.S.P.Q. 2d 1565, 1567 (Fed Cir. 1995).

Smith discloses mouse cellular retinol binding protein (CRBP) cDNA in Figure 1(A). There is no evidence of record that mouse CRBP cDNA will specifically bind to SEQ ID NO:1, SEQ ID NO:4, or the complements thereof. The ATGAGAATTCGA embedded within CRBP cDNA is but a tiny part of the full length cDNA and it does not exist without the flanking sequence. It only exists as information. It does not exist as a polynucleotide that falls within the scope of the claims.

Claim 20 requires that the nucleic acid be (1) isolated; and (2) specifically bind to a polynucleotide of SEQ ID NO:1 or 4, or the complements thereof. Smith fails to meet either of these limitations. The Smith ATGAGAATTCGA sequence is not isolated, and in its present form it does not specifically bind to a polynucleotide of SEQ ID NO:1 or 4, or the complements thereof.

In other words, the Smith reference does not disclose a 12 nucleotide portion of a nucleic acid. The reference teaches a polynucleotide of over 592 nucleotides. This polynucleotide would not specifically bind or form a stable complex in the manner required by the claims. Smith does not call out or teach the oligonucleotide ATGAGAATTCGA. In fact, this oligonucleotide is within a larger underlined sequence used for screening; see legend to Figure 1(A) at page 2224 of Smith. According to Smith, the ATGAGAATTCGA noted by the Examiner would be flanked by enough bases to prevent stable duplex formation with the polynucleotides recited in the present claims.

Smith does not teach an isolated oligonucleotide of ATGAGAATTCGA. Furthermore, Smith represents a different protein art (cellular retinol binding protein) and one of skill would not look to a cellular retinol binding protein for teaching of an oligonucleotide capable of specifically binding to IL-15. The use of the Smith reference

is a construct of electronic sequence searching and bears no relationship to real life anticipation in the art.

The Examiner has stated on previous occasions (Office Action mailed January 8, 2003; Advisory Action mailed December 24, 2003) that claims 20-30 were not subject to prior art rejections and were allowable or allowed. The 1991 Smith reference is an anomaly of searching and does not represent true anticipatory art because the twelve nucleotide sequence not isolated, and instead is embedded within a much longer sequence. The reference fails to teach isolation of the cited sequence, and it teaches no function whatsoever outside the cellular retinol binding protein. It is as if a claim directed to a walking stick was alleged to be anticipated by one leg of a chair, wherein the leg alone does not exist within the chair reference, and the chair has no teaching to remove one leg for a totally different use.

The fact that the claims have been allowable and allowed following prior art searches at earlier stages in the prosecution testifies to the arbitrariness of citing an embedded short oligonucleotide, in a 1991 reference disclosing Cellular Retinol Binding Protein, against claims directed to IL-15 sequences.

Reconsideration and withdrawal of the rejection are respectfully requested.

If fees are believed necessary, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 04-0258. A duplicate copy of this document is enclosed.

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

If questions remain regarding this application, the Examiner is invited to contact the undersigned at (206) 628-7650.

Respectfully submitted,
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